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UNITED STATES DISTRICT COURT
EASTERN DISTRICT of PENNSYLVANIA

IRENE KLIMKIEWICZ BELFERT
and MICHAEL BELFERT

Plaintiffs,

v.

MAQUET HOLDING B.V. & CO. KG ,
MAQUET CARDIOVASCULAR,LLC.
MAQUET INC.
MAQUET GETINGE GROUP USA.
GETINGE HOLDING USA INC .
GETINGE HOLDING USA 11 INC.
Defendants,

Case No: 15 3931

COMPLAINT

DEMAND FOR JURY TRIAL

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COMPLAINT FOR DAMAGES PURSUANT TO 28 U.S.C §1332
CAUSATION FOR DAMAGES PURSUANT TO 21 USC §810.15

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction based on diversity of the parties, and the amount in controversy exceeds $75,000.00 as required under 28 U.S.C. § 1332(a)(2).

2. Venue in this Court is proper under 28 U.S.C. § 1391(a) as the injury and transaction giving rise to the claims set forth herein.

PARTIES

3. Plaintiffs,
Irene Klimkiewicz Belfert and Michael Belfert are individuals with an address of 1105 Tree St. Philadelphia, PA. 19148

4. Defendants,
("Maquet Cardiovascular, LLC" et al., or "defendants"), is an LLC organized and existing under the laws of the State Delaware, having its United States headquarters at 45 Barbour Pond Drive Wayne, NJ 07470 U.S.A.

BACKROUND

5. Maquet Cardiovascular LLC is the developer and manufacturer of Electrosurgical, Cutting & Coagulation & Accessories. Maquet Getinge Group USA is the developer and manufacturer of Cardiosave CS300 Intra-Aortic Balloon Pumps & Sensation Intra-Aortic Balloon Pump accessories.
Vasoview Endoscopic Vessel Harvesting Medical Devices and Maquet Getinge Intra-Aortic Balloon pumps & accessories were recently recalled Nationally after many reports of causing injury to patients, various malfunctioning issues and serious device defects. Maquet Cardiovascular was recently cited by the FDA for numerous violations during repeated inspections conducted at their manufacturing facility located in Wayne New Jersey for non compliance with FDA Laws.

(a) On April 1, 2012 The United States of America by its attorneys, filed a complaint for permanent injunction against Atrium Medical Corp., Maquet Holding B.V. & Co. KG, Maquet Cardiovascular LLC., Maquet Cardiopulmonary AG Corporations, CEO, Managing Director Heinz Jacqui, Corporate Chief Quality Assurance Regulatory Affairs and Compliance Officer at Maquet Collectively. The complaint alleging numerous violations of the Food, Drug and Cosmetic Act 21 U.S.C.

(b) The FDA Department Of Health And Human Services conducted Twenty eight (28) inspections from 7/01/2013 to 10/16/2013 at Maquet Cardiovascular, LLC, Medical Device facility located in Wayne, New Jersey. Investigators again and again made observations sited on Form FDA-383 Reports include, complaints regarding numerous malfunction and Device Failure incidents. Particularly malfunctioning, Vasoview, VasoView 6, and Vasoview Hemopro causing the most serious injuries and some patient deaths.

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FACTUAL ALLEGATIONS

6. At all relevant times, Maquet Cardiovascular, LLC did business in Pennsylvania and distributed Vasoview Endoscopic Medical Surgical Devices to locations throughout the United States, including Pennsylvania .

(a)At all relevant times, Maquet Cardiovascular, LLC., Maquet Getinge, USA designed, manufactured and distributed Electrosurgical, Cutting & Coagulation Medical Devices, Intra-Aortic Balloon Pumps & Accessories. Including the following: Guidant Vasoview endoscopic Vessel Harvesting Medical Devices: Vasoview 6 Pro EVH System, Vasoview 7 EVH System, Vasoview Hemopro 2 EVH System and Vasoview Hemopro EVH System.

7. On July 27, 2013, Plaintiff Irene Klimkiewicz Belfert 72 years old, underwent Emergent coronary bypass x4 with reverse saphenous vein grafts to the diagonal one, obtuse marginal 1, right coronary artery, and left internal mammary to the left anterior descending.

8. The Plaintiffs Coronary bypass procedure was performed on July 27, 2013 at Thomas Jefferson University Hospital in Philadelphia, Pennsylvania by SURGEON: Dr. James T. Diehl, MD. - ASSISTANT: Shinya Unai, MD and Amanda Pickles PA-C

9. Plaintiff, Irene Klimkiewicz Belfert's Greater saphenous vein was harvested from her left leg using the Vasoview endoscopic technique with the Vasoview Vein Harvesting Medical device.

10. The operative report dated July 29, 2013 dictated by Dr. James Diehl MD, states the details of the procedure performed on July 27, 2013. The report states that there were no complications, during or after the coronary bypass surgery.

11. However, in the discharge report dated August 4, 2014, states that at 9:15p.m., approximately 15.75 hours following surgery, Plaintiff was exbutated and plans were made for the Intra-Aortic Balloon Pump removal.

12. However the Plaintiff had developed a cold Left leg where the Balloon Pump had been placed. It was determined that the Intra-Aortic Balloon Pump had ruptured. The Intra-Aortic Balloon Pump had to be Emergently removed. The Plaintiffs pulse was returned to her left leg. The plaintiff was Hymodynamically supported with Epinehrine and Milrinine. The report states that the Plaintiff had no further complications regarding leg Ishemia following this incident.

13. Plantiff, Irene Klimkiewicz Belfert was then discharged from Thomas Jefferson University Hospital on August 4, 2013. At that time she complained to the hospital staff of suffering severe pain at the vein harvesting site in her Left leg and ankle.

14. While recovering at her home,The Plaintiff became very worried and concerned when vein harvest site injury became more and more infected,causing severe pain and was not healing, posing a potentially life threatening injury.

15. After the plaintiff had several follow up visits and conversations with the hospital and cardiology department staff. Dr. Diehl MD prescribed antibiotic

treatment for the injury. The antibiotics failed to help.The Plaintiff was then scheduled to have a second procedure on September 14, 2013.

16. On September 14, 2013, Dr. James Diehl Performed a Debridment procedure on The Plaintiffs left leg at the original vein harvesting site. The procedure caused the plaintiffs leg wound even more extensive and excruciating pain.

17. The vein harvesting injury caused the Plaintiff, Irene Klimkiewicz Belfert permanent nerve damage to her left leg. This injury is the result of the defective Vassoview Medical device used in the vein harvesting procedure on July 27, 2013. Maquet Cardiovascular LLC et al. is liable for negligence and damages caused by the Medical Device.

COUNT I

Irene Klimkiewicz Belfert and Michael Belfert

v.

Maquet Cardiovascular, LLC et al.

STRICT PRODUCT LIABILITY

18. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein U.S.C.. 21. §810.15

19. At all times relevant hereto, Maquet Cardiovascular, LLC was in the business of developing, testing, marketing, promoting and utilizing the Vasoview Endoscopic Vessel harvesting System devices.

20. Maquet Cardiovascular,LLC, tested, marketed, promoted and/or sold the Vasoview Devices utilized during plaintiffs surgery. Dr. James Diehl M.D performed the procedure with the Vasoview Vessel Harvesting procedure on the plaintiff.

21. Upon information and belief, the procedure utilized in surgery were expected to perform without complications during the vein harvesting procedure at the facility in which it was intended by the surgical team.

22. Maquet's Vassoview vessel harvesting device was deficient in at least the following particulars:

(a) the Device was defective and/or unreasonably dangerous when inserted in plaintiff;

(b) the Device was not accompanied by adequate or explicit labeling;

(c) the Devices advertising and promotional materials contained misrepresentations of material facts and/or failed to contain sufficient material facts necessary for researchers and/or subjects to make informed decisions regarding its selection and use;

(d) sufficient material facts necessary for researchers and/or subjects to make informed decisions regarding its selection and use;

(e) the dangers associated with the use of the Vasoview Device on plaintiff exceeded the potential benefits;

(f) the defendant failed to adequately test the system in the face of known consequences;

(g) the defendant allowed the Device to be used and inserted in plaintiff while knowing its dangerous propensities;

(h) failing to warn users of the dangers inherent in using the product;

(i) failing to fix the conditions which increased the risk of harm to the patient.

during the times when this product was being distributed to various physicians; and

(j) being otherwise careless and negligent in the design and conduct of the Device.

23. By reason of the carelessness and negligence of defendant, as stated above, plaintiff was proximately caused to sustain severe, critical, physical and personal injuries.

24. As a direct and proximate result of defendant's actions, as set forth above, plaintiffs, Irene Klimkiewicz Belfert and Michael Belfert have in the past been, and will in the future continue to be compelled to expend monies and incur obligations for medical care and treatment; plaintiffs, have also incurred and will

hereafter continue to incur other financial expenses or losses which do or may exceed amounts which she may otherwise be entitled to recover.

25. Plaintiffs, Irene Klimkiewicz Belfert and Michael Belfert have sustained and makes claims for pain and suffering, loss of physical function, permanent physical, mental, dignitary and psychological injuries, loss of life's pleasures, loss of earning capacity, and any and all the damages to which she is or may be entitled under the law of the State of Pennsylvania.

WHEREFORE, plaintiffs, Irene Klimkiewicz Belfert and Michael Belfert make claims of defendant Maquet Cardiovascular LLC et al., Punitive and Compensatory damages, interest, allowable costs of suit, a trial by jury and such other further relief as the court deems appropriate.

COUNT 11

Irene Klimkiewicz Belfert and Michael Belfert

v.

Maquet Cardiovascular, LLC et al.

NEGLIGENCE

26. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein U.S.C. 21. §810.15

27. Maquet Cardiovascular LLC had a duty to plaintiff to use reasonable care in designing,manufacturing, marketing, labeling, packaging and selling Vasoview Endoscopic Vessel Harvesting Medical Devices.

28. Maquet Cardiovascular, LLC et al.was negligent in failing to use reasonable care in designing, manufacturing, marketing, labeling packaging and selling Vasoview Vessel Harvesting Medical Devices. Maquet Cardiovascular, LLC, et al. Breached its aforementioned duty under U.S.C. 21 §810.15 among other things:

(a) Failing to design Vasoview Vessel Harvesting Devices so as to avoid unreasonable risk of harm to patients whom the Device was used, including plaintiff;

(b) Failing to manufacture the medical Devices so as to avoid an unreasonable risk of harm to patients , including plaintiff;

(C)

harm to patients, including plaintiff;

(d)

of harm patients whom the Device was used, including plaintiff;

(e) failing to use reasonable care in inspecting the device so as to avoid an unreasonable risk of harm.

(f) Failing to use reasonable care in the training and instruction to physicians for the safe use of the products;

(g)

determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable;

and

(h)

or selling The Vasoview Vessel Harvesting Device.

29. Maquet Cardiovascular, LLC also negligently failed to warn or instruct plaintiffs and/or her healthcare providers of the actual risk.

30. Maquet Cardiovascular, LLC also is responsible for the false and misleading representation for neglect actions.

31. As a direct and proximate result of defendants negligence, plaintiffs have experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses, lost income and other damages.

DEMAND FOR JURY TRIAL

PRAYER FOR RELIEF:

WHEREFORE, Plaintiffs respectfully pray for a judgment against Defendants for: plaintiffs, Irene Klimkiewicz Belfert and Michael Belfert claims of defendants, Punitive and Compensatory damages, interest, allowable costs of suit, a trial by jury and such other further relief as:

1. Injunctive and equitable relief as the Court deems appropriate including:
2. Compensatory damages to be paid by all Defendants, according to proof at trial;
3. Punitive damages as the court deems appropriate;
4. Consortium damages to children family members;.
5. Costs and attorneys fees of this lawsuit, with interest;
6. Any other relief as the court deems appropriate.

Plaintiffs, In Pro Se:

Dated: July 4, 2015

Irene Klimkiewicz

Irene Klimkiewicz Belfert
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Philadelphia PA. 19148.
(215) 336-5653

Dated: July 4, 2015

Michael Belfert

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